REMARKS

Claims 1 and 3-34 are pending in the application. Claims 14-32 have been withdrawn from consideration as being subject to nonelected inventions.

Claims 1, 3-13, 33 and 34 are subject to examination. Claims 33 and 34 are newly added, and are properly grouped in the elected group. Basis for the new claims is provided at page 8 lines 4 to 7.

The claims have been amended to improve their clarity, including replacing "fluorogenic fragment" with "fragment". Claims 1 and 12 have been amended, as suggested by Examiner, to recite the pentapeptide amino acid sequence in the form "GGGGS (SEQ ID NO:1)". The same change has been made to withdrawn claims 14 and 26.

Response to Restriction Requirement

The Examiner makes the restriction requirement final, alleging that Applicants did not point out errors in the restriction requirement. Applicants, however, did request timely rejoinder, as appropriate. Because the present application is a National Stage application, 37 C.F.R. § 1.475 applies. Groups I and III (withdrawn claims 24-29) are related as product (i.e., protein interaction system) and first recited method of using the product. 37 C.F.R. § 1.475(b)(2) thus mandates rejoinder of Groups I and III. The same is respectfully requested.

Response to 35 USC 112, 2nd Paragraph Rejection

The rejection under 35 USC 112, 2nd paragraph has been maintained. The Examiner has indicated it is considered to be unclear what is required to have the first fragment of fluorescent protein functionally associate with the complementary fragment of fluorescent protein.

As the Examiner indicates, the dictionary definition of "associate" is "to join or connect together". As clearly understood by the Examiner, as noted in the art and therefore understood by a person of ordinary skill in the art, and as stated in the application as filed, when appropriate fragments of a fluorescent protein associate with each other, having been correctly brought together, the two fragments, which by themselves do not provide fluorescence, can function as a

single entity and generate fluorescence. The term "functionally" acts to clarify the association of the fragments should result in fluorescence rather than define the way in which the association should occur.

The phrase "functionally associated" is used to clarify the association which promotes fluorescence, rather than any other form of association in which the fragments come together, but which does not provide fluorescence. As it is known in the art that such association can occur, and as the specification clearly sets out on pages 10 and 11 the split points in the humanised form of Green Fluorescent Protein (SEQ ID NO 2) which can provide fragments, which when brought together "associate" such that fluorescence is generated, the phrase "functionally associated" is considered to be clear.

Reconsideration and withdrawal of the Section 112, 2nd paragraph rejection is respectfully requested.

Response to "New Objection"

Claims 1 and 12 have been objected to under par. 26 of the Detailed Action as to the form of the representation of the pentapeptide amino acid sequence. The claims have been amended as suggested by Examiner.

Response to 35 USC 112 1st Paragraph Rejection - Written Description

Claims 1, 3 and 5-13 remain rejected under 35 U.S.C. 112, 1st paragraph, as allegedly failing to comply with the written description requirement. Reconsideration is requested in view of the following remarks.

GROUNDS FOR REJECTION

The Examiner applies the wrong standard of law to determine compliance with the written description requirement of 35 U.S.C. § 112, first paragraph. Office Action, pp. 5-7, par. 1. The Examiner provides 13 pages of conclusory remarks and allegations regarding the scope of the claims, the variety of species encompassed by the claim terms, and the description provided in the specification. The Examiner concludes that the generic expressions "bait fusion proteins," "fluorogenic fragment of fluorescent protein," "first peptide of interest," "linker

protein," "prey fusion protein," "second peptide of interest," and "second linker" do not provide ample written description for the "compounds" since the claims do not describe a single structural feature. The Examiner also discusses U.S. Published Application No. 2002/0146701 A1 ("Hamilton") at the paragraph bridging pp. 17-18. For the sake of economy, Applicants will not characterize or discuss each of the Examiner's statements. Applicants do not thereby acquiesce to the correctness of any of the Examiner's assertions.

ARGUMENT

Standard of Law:

The Examiner cites MPEP § 2163¹ but misapplies the guidelines and principles set forth to determine compliance with the written description requirement. MPEP § 2163 notes that there is a strong presumption that an adequate written description of the claimed invention is present when the application is filed, which the USPTO may rebut only with evidence or reasons.² MPEP § 2163 further states that examiners should apply the holding in *Falkner v. Inglis*, 448 F.3d 1357, 1366, 79 USPQ2d 1001, 1007 (Fed. Cir. 2006) (emphasis added):

- (1) examples are not necessary to support the adequacy of a written description;
- (2) the written description standard may be met even where actual reduction to practice of an invention is absent; and
- (3) there is no per se rule that an adequate written description of an invention that involves a biological macromolecule must contain a recitation of known structure.

Where claimed biological macromolecules are novel combinations of *known segments*—as in the present case—MPEP § 2163 notes that specifications may meet the written description requirement without providing any "structure or formula or chemical name for the nucleotide

Although, the MPEP "does not have the force of law or the force of the rules of Title 37 of the Code of Federal Regulations," MPEP Foreword (8th ed., rev. 7, Aug. 2008), it "is made available to the public and . . . describe[s] procedures on which the public can rely." *In re Skvorecz*, 92 USPQ2d 1020, 1024, n.3 (Fed. Cir. 2009).

In re Wertheim, 541 F.2d 257, 263, 191 USPQ 90, 97 (CCPA 1976) ("we are of the opinion that the PTO has the initial burden of presenting evidence or reasons why persons skilled in the art would not recognize in the disclosure a description of the invention defined by the claims").

sequences of the claimed chimeric genes." Instead, compliance with the written description requirement is determined on the basis of the *Capon* factors:

Precedent illustrates that the determination of what is needed to support generic claims to biological subject matter depends on a variety of factors, such as the existing knowledge in the particular field, the extent and content of the prior art, the maturity of the science or technology, the predictability of the aspect at issue, and other considerations appropriate to the subject matter.

It is not necessary that every permutation within a generally operable invention be effective in order for an inventor to obtain a generic claim, provided that the effect is sufficiently demonstrated to characterize a generic invention.⁴

Applicants stated the proper legal standard in the response filed May 18, 2009. The Examiner, however, makes no attempt to distinguish any of the cases cited by Applicants. No federal agency—including the USPTO—is "free to refuse to follow circuit precedent." Actions by a federal agency that are contrary to precedent are reversed as unlawful, when reviewed under the "arbitrary and capricious" standard of 5 U.S.C. § 706(2)(a).

The Examiner's refusal to follow precedent in this case leads the Examiner to make unnecessary requirements for "structural formulae" and a "sufficient number of representative [examples]." Further, the Examiner focuses the analysis almost exclusively on the "vast" scope

MPEP § 2163 (citing Capon v. Eshhar, 418 F.3d 1349, 1358, 76 USPQ2d 1078, 1084 (Fed. Cir. 2005)); compare Univ. Rochester v. G.D. Searle & Co., 358 F.3d 916, 926-27, 69 USPQ2d, 1886, 1894-95 (Fed. Cir. 2004) (finding inadequate written description, where the disclosure provided nothing more than a "hoped-for function for an as-yet-to-be-discovered compound, and a research plan for trying to find it").

⁴ Capon, 76 USPQ2d at 1085.

See, e.g., In re Lee, 61 USPQ2d 1430, 1434 (Fed. Cir. 2002) (relying on National Labor Relations Bd. v. Ashkenazy Property Mgt. Corp., 817 F.2d 74, 75 (9th Cir. 1987)).

[&]quot;There is strong authority for the proposition that agency action inconsistent with its own precedent is arbitrary and capricious." *Groz v. Quigg*, 10 U.S.P.Q.2d 1787, 1789 (D.D.C. 1988). Agency decisions that depart from established precedent without a reasoned explanation or that fail to cite any statutory or decisional authority for its assumptions will be vacated as arbitrary and capricious. *Graphic Communications Int'l Union, Local 554 v. Salem-Gravure Div. World Color Press, Inc.*, 843 F.2d 1490, 1493 (D.C. Cir. 1988).

The Examiner admits that the MPEP provides no basis for determining how many examples are "representative" (Office Action, p. 6, par. 4). The Examiner attempts to fill this logical gap by reliance on *In re Gosteli*, 872 F.2d 1008, 1012, 10 USPQ2d 1614, 1618 (Fed. Cir. 1989) for the proposition that a disclosure of two species *per se* cannot adequately describe a genus. The court in *Gosteli made no such* per se *rule*. The issue in *Gosteli* was whether prior invention of two species also disclosed in the prior art would suffice to antedate the prior art reference under 35 U.S.C. § 119. The number of species "representative" of a genus was not at issue in *Gosteli*.

of the claims. The relevant analysis, however, is whether the degree of exemplification in the specification provides an adequate description of the breadth of each claim, in light of "the existing knowledge in the particular field, the extent and content of the prior art, the maturity of the science or technology, the predictability of the aspect at issue."

The Capon factors are clearly similar to the Wands factors. Yet the Examiner acknowledges that the claims are enabled, in light of the Wands factors. See Office Action, p. 2. Faced with a comparable inconsistency on the part of the USPTO, the Federal Circuit noted that an analysis focusing on whether an application provides merely an invitation to experiment (see Office Action, p. 18, par. 2) is more relevant to enablement than written description. The present rejection should be withdrawn for this reason alone, as it was revered in Capon.

Because this is the third Office Action issued in this application, and because the Examiner still refuses to apply binding legal precedent, Applicants respectfully invoke the procedures set forth in MPEP § 707.02, which requires all subsequent Office Action to be issued with a supervisor's signature.

Applicants now apply the correct legal standard to the issue of written description.

Analysis of the Capon Factors:

(i) "fluorogenic fragment of fluorescent protein"

Fluorescent proteins are a well-characterized genus of molecules. As noted by the Examiner, the specification identifies examples of fluorescent proteins, such as RFP, BFP, YFP and CFP, and variants of GFP. Thus, the specification, in view of the knowledge of the art, provides an adequate written description of the genus of fluorescent proteins. *See Capon*, 76 USPQ2d at 1085.

The expression "fluorogenic fragment of fluorescent protein" is likewise supported by the written description of the specification, given the knowledge of the art. The specification teaches, for example:

Capon, 76 USPQ2d at 1085 ("It is well recognized that in the 'unpredictable' fields of science, it is appropriate to recognize the variability in the science in determining the scope of the coverage to which the inventor is entitled. Such a decision usually focuses on the exemplification in the specification.")

Capon, 76 USPQ2d at 1086.

Any fluorescent protein in which appropriate split sites can be formed and which the resulting fragments can associate with each other and cause fluorescence may be used in the invention. (Specification, p. 9, ll. 22-24.)

The expression encompasses a fragment of a fluorescent protein embracing the structural feature that the fragment may functionally associate with a complimentary fragment to generate a fluorescent signal. A person skilled in the art would be aware that fluorescent proteins may be cleaved to form two fragments, which may functionally associate with each other when brought together in the appropriate orientation and form a species capable of generating a fluorescent signal. A person skilled in the art would also appreciate that the split point where the fluorescent protein is to be cleaved to originate the two fluorogenic fragments is to be chosen judiciously, so that the two fluorogenic fragments are able to functionally associate with each other when brought together in the appropriate orientation and generate a fluorescent signal after such functional association.

The specification describes a representative sub-genus of "fluorogenic fragment of fluorescent protein" at length at page 11 with regard to the Enhanced Green Fluorescent Protein (EGFP), a well-known fluorescent protein. Approximately 14 potential split points in EGFP are described giving rise to fluorogenic fragments. In view of this teaching provided for EGFP, a representative fluorescent protein, and armed with the level of knowledge and predictability in the art, the skilled person would know how to generate and test suitable split points in other fluorescent proteins to obtain fluorogenic fragments. There is no legal requirement to show reduction to practice for all the embodiments encompassed by a generic claim. See, e.g., Falkner, 448 F.3d at 1366, 79 USPQ2d at 1007. In particular, the Examiner has provided no relevant evidence or reasoning that this art is unpredictable that the description of EGFP fragments cannot be generalized to other fluorescent proteins. See Capon, 76 USPQ2d at 1085. Thus, the genus at issue is adequately described.

Instead, the Examiner alleges U.S. Published Application No. 2002/0146701 A1 ("Hamilton") provides rebuttal evidence. The portion of Hamilton cited by the Examiner (par. 8) pertains to the insertion of a hexapeptide into GFP loops by Abedi and co-workers:

fluorescence. Abedi et al. (1998, Nucleic Acids Res., 26, 623-30) have inserted peptides between residues contained in several GFP loops. Inserts of the short sequence LEEFGS (SEQ ID NO: 9) between adjacent residues at 10 internal insertion sites were tried. Of these, inserts at three sites, between residues 157-158, 172-173 and 194-195 gave fluorescence of at least 1% of that of wild type GFP. Only inserts between residues 157-158 and 172-173 had fluorescence of at least 10% of wild type GFP.

Abedi inserted hexapeptides into GFP and unsurprisingly found that the native GFP structure was disrupted; however, Abedi did not form GFP fragments connected to other proteins by linkers. The cited disclosure in Hamilton is irrelevant to the level of unpredictability of making *fragments* of GFP, or any other protein. As noted above, the specification discloses ample examples of EGFP fragments. Even Hamilton discloses GFP fragments. The Examiner has provided no relevant reasoning or evidence to question the adequacy of the written description in this regard. *See Wertheim*, 541 F.2d at 263, 191 USPQ at 97. The claims thus must be considered adequately described. *See Capon*, 76 USPQ2d at 1085.

(ii) "first peptide of interest" and "second peptide of interest"

The claims are directed to a general screening method which may be used to determine interactions between unknown proteins. From the teaching on page 13 of the specification, for example, a peptide of interest may be a small peptide or a full size protein, and these may be provided in different ways. Furthermore, as supported throughout the specification, such as on page 6, lines 5-7, in one embodiment of the invention there is provided a screening method that may be used to determine whether and/or how the first peptide of interest and the second peptide of interest interact. Practice of the claimed invention thus does not require prior knowledge of the possible interaction of the peptides of interest, let alone knowledge of the amino acid sequence or structure of the peptides of interest.

The specification describes a successful application of the claimed approach to demonstrate multiple protein interactions with membrane glycoproteins of Measles Virus. See, e.g., Specification, Example 3. The specification asserts that further protein interactions could be detected using the same methodology (p. 40, ll. 20-25):

It is clear that this methodology could be used to identify further membrane receptor proteins which interact with the H proteins as could cytoplasmic proteins

which interact with known MV receptors and which may therefore initiate downstream signaling events.

The Examiner provides no relevant evidence or reasoning, in light of the proper legal standard, to question whether the examples in the specification are predictive of the ability to identify protein interactions in other systems. Accordingly, the terms "first peptide of interest" and "second peptide of interest" are adequately described, and the description reasonably conveys to a skilled artisan that the inventor, at the time the application was filed, had possession of the entire scope of the claimed invention.

(iii) "linker portion" and "second linker portion"

Without acquiescing in the rejection, and in an effort to advance prosecution, claim 1 has been amended to more clearly define the structure of the "linker portion" and "second linker portion." Amended claim 1 specifies that the linker portion and the second linker portion independently comprise multiples of a pentapeptide sequence glycyl-glycyl-glycyl-glycyl-serine (GGGGS). The amendment is supported in the specification at page 9, lines 17-20. The amendment overcomes the ground of rejection as to the alleged lack of adequate written description for the terms "a linker portion" and "a second linker portion."

(iv) "bait fusion protein" and "prey fusion protein"

A "bait fusion protein" is recited in claim 1 as comprising a first fluorogenic fragment of fluorescent protein, a first peptide of interest, and a linker portion interposed between the first peptide and the first fluorogenic fragment. A "prey fusion protein" is recited in claim 1 as comprising a second fluorogenic fragment of fluorescent protein, which is complementary to the first fluorogenic fragment of fluorescent protein, a second peptide of interest, and a linker portion interposed between the second peptide and the second fluorogenic fragment.

As discussed above, Applicants submit that the specification provides adequate written description for each of the components. Accordingly, the specification also provides adequate written description for the terms "a bait fusion protein" and "a prey fusion protein."

As acknowledged by the Examiner, at page 10 of the office action, the application discloses in Example 2 details of a protein interaction system as claimed, having suitable

fluorogenic fragments of GFP, linkers of varying lengths, and exemplary leucine zipper proteins known to interact, wherein such leucine zipper proteins correspond to the first peptide of interest and second peptide of interest. This exemplary model of the protein interaction system provides a proof of the principle of the claimed system, since the ability of the fluorogenic fragments to interact and generate fluorescence was, in one aspect, associated with the fact that the leucine zipper proteins bind to each other. The amino acid sequences of the leucine zipper proteins or knowledge of their structures are immaterial for the implementation of the invention. This example thus demonstrates that other bait and prey protein combinations may be used. While the Examiner notes that this means the numbers of possible prey and bait proteins are vast, as these prey and bait proteins will be attached to the respective linkers in the same way, the actual amino acid sequences of the bait and prey proteins are immaterial to putting the invention into effect.

The Examiner has asserted that the specification does not describe the kind or size of different proteins from the myriad of known proteins that can be fused to GFP without destroying the function of GFP. However, in one embodiment of the invention, linkers of suitable length and character are provided, as defined in the amended claim, such that, in contrast to the prior art, any proteins may be selected as bait and prey peptides of interest as they will not prevent the binding of fluorogenic fragments.

As pointed out in the previous section, the amendment of claim 1 with respect to the structural characteristics of the linker and second linker is believed to overcome the Examiner's objection.

It is therefore submitted that the specification successfully conveys to a person skilled in the art that the inventors had possession of the entire scope of the claimed invention at the time the application was filed. Applicants further submit that the nature of the invention does not allow for further structural definitions of the technical features of claim 1 without unduly restricting the scope of the claims.

In summary, Applicants submit that the claims as amended are supported by an adequate written description. Reconsideration and withdrawal of the rejection of claims 1, 3 and 5-13 under 35 U.S.C. § 112, first paragraph, for alleged lack of written description is respectfully requested.

Response to 35 USC 103 Rejection

Claims 1 and 3-13 have been rejected as allegedly unpatentable over Hu *et al.* in view of Hamilton *et al.*, as evidenced by http://www/biovioisno.com/updated/egfp.html ("BioVision") in view of Michnick *et al.* (U.S. Published Application No. 2005/01617687 A1).

The claims as amended require a plurality of bait fusion proteins to be present wherein the linker portions of at least two bait fusion proteins are of different lengths and comprise multiples of the pentapeptide sequence SEQ ID NO 1.

The Examiner indicates at par. 20 of the Detailed Action report that Hu et al teaches a composition comprising proteins fused to different fragments of yellow fluorescent proteins (YFP) connected by linker peptides of different lengths for example KQKVMNH and RSIAT (p797 left column).

However, from the teaching identified by the Examiner, it is clear the RSIAT linker connects the N terminus of YFP b-Jun (a first peptide of interest) to form a bait construct. It is clear that KQKUMNH connects YFP (complementary fragment of fluorescent protein) to b-Fos (a second peptide of interest) to form a prey construct. The bait-prey relationship of b-Jun and b-Fos, which causes the functional association of the fragments of YFP, is clearly illustrated at Figure 1A, page 790 of Hu et al.

Hu et al only describes the use of single linker length attached to a first peptide of interest protein and a single linker length attached to a second peptide of interest. As will be appreciated while b-Fos or b-Jun, could be a first peptide of interest, both cannot be considered as the first peptide of interest at the same time. One must be a first peptide of interest to form a bait fusion protein and the other must be a second peptide of interest to form a prey fusion protein. Thus, the requirement of claim 1 that at least two bait fusion proteins have linker portions of different lengths is neither taught nor suggested by Hu.

Hamilton does not remedy the deficiencies of Hu et al. Hamilton discusses a pair of helices, NZ and CZ, capable of forming an antiparallel leucine zipper wherein NZ is connected via a linker to a GFP fragment and CZ is connected via a linker to a GFP fragment.

If NZ is considered to be a first peptide of interest, it is not conjoined to the fragment of fluorescent protein by more than one length of linker (Hamilton only discusses a 6 residue linker between C-terminal of NGFP and NZ). Similarly if CZ is considered to be a first peptide of interest, it is not conjoined to the fragment of fluorescent protein by more than one length of linker (Hamilton only discusses a 4 residue linker between CGFP and CZ).

CZ and NZ cannot be considered to be bait fusion constructs at the same time, as they have complementary fragments of fluorescent protein.

Thus, Hamilton does not teach the claimed subject matter.

The deficiencies of Hu et al and Hamilton are not remedied by Michnick et al. Michnick et al suffers from the same deficiency as Hue et al. and Hamilton in that like Hu et al, and Hamilton, it only teaches the use of a single length of linker. Michnick et al. does not teach the use of at least two different linker lengths interposed between a first peptide of interest and a fragment of fluorescent protein in a bait fusion protein.

At paragraph 32 of the Detailed Action, the Examiner has asserted that it would have been obvious to one of ordinary skill in the art to "try different linker lengths for optimal lengths for the fluorescent fragments to reassociate with each other to generate fluorescent signal." Obviousness must be shown by objective evidence. See, e.g., In re Zurko, 59 U.S.P.Q.2d 1693, 1697 (Fed. Cir. 2001). No evidence is provided to support this assertion.

Further, there is no suggestion that this optimization should be performed by providing a system in which different lengths of linker are included which are attached to a first peptide of interest, as opposed to conducting testing to determine an optimal linker length and then only using this linker length in further assays to determine binding. None of the cited documents suggest any advantage conferred by providing linkers of different lengths between a first peptide of interest and a fragment of fluorescent protein in a protein interaction system as claimed.

The benefits of providing a range of linker lengths over a single linker length are detailed in the specification at page 7, lines 12-22. A range maximizes the chances of an interaction between peptides of interest being detected. A range of linker lengths also minimizes the chances that fluorescent fragments cannot associate with each other due to stereochemical

hindrance, or that the linkers are too flexible (too long) to bring the fluorescent fragments together in space, despite that the proteins of interest are interacting.

None of the references even recognize the problems that are solved by providing linkers of different lengths. "The determination of whether a novel structure is or is not 'obvious' requires cognizance of the properties of that structure and the problem which it solved, viewed in light of the teachings of the prior art." In re Wright, 6 USPQ2d 1958, 1961-62 (Fed.Cir.1988) (emphasis added). In the absence of an appreciation of the problem solved, that solution can not be obvious. See, In re Shaffer, 108 USPQ 326, 329 (CCPA 1956):

In fact, a person having the references before him who was not cognizant of appellant's disclosure would not be informed that the problem solved by appellant ever existed. Therefore, can it be said that these references which never recognized appellant's problem would have suggested its solution? We think not, and therefore feel that the references were improperly combined since there is no suggestion in either of the references that they can be combined to produce appellant's result.

One of ordinary skill in the art would, in fact, be led away from the present invention by the asserted prior art. Hamilton at paragraph [0012] contains the following teaching regarding linkers:

[A] linker having 4-6 amino acids is sufficient. Similar attachment of parallel leucine zippers should require >10 amino acids to span the necessary distance. The long unstructured linkers would be prone to proteolytic cleavage and be less stable in in vivo assays,

Based on this teaching, the person of skill in the art would be led away from providing different lengths of linkers in a protein interaction system as claimed, wherein the linkers comprise multiples of the pentapeptide sequence SEQ ID NO 1. The skilled artisan would consider that linkers comprised of multiples of the pentapeptide SEQ ID NO:1 would risk linker cleavage, and unclear assay results.

Indeed, Hamilton appears to suggest binding of the leucine zipper in a particular orientation would not allow the fragments to come together and that increasing the linker length would not solve this problem. In contrast, the inventors have realized the advantageous nature of providing linkers of different lengths to provide a robust system which overcomes the orientation

problem discussed in Hamilton. The inventors have selected appropriate amino acids to form the linkers.

Moreover, Michnick, which considers the use of a flexible linker between the gene of interest and the reporter, indicates the flexibility of the linkers discussed therein ensures that the orientation and arrangement of the fragments is optimal to bring the protein fragments in close proximity. The use of multiple linkers of different lengths between a peptide of interest and a fragment of fluorescent protein is not suggested by Michnick. In view of Michnick's focus on linker flexibility to ensure orientation and arrangement of fragments into close proximity, the person of ordinary skill in the art would not consider the use of multiple linkers of different lengths as advantageous, and would not be motivated to include multiple linker lengths.

Accordingly, Applicants submit that claim 1 as amended is allowable over the combination of Hu et al. and Hamilton et al., as evidenced by BioVision, and further in view of Michnick. Claims 3 to 13 are dependent on claim 1 and therefore also therefore allowable over the asserted combination of references. The same is true of new claims 33 and 34, which depend from claim 1.

Conclusion

The claims remaining in the application are believed to be in condition for allowance. An early action toward that end is earnestly solicited.

Respectfully submitted,

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